# EXHIBIT 91

To: Debra Swartz Date: November 8, 2010

**Senior Counsel** 

**AmerisourceBergen Corporation** 

Fm: Michael R. Mapes

**CSRA DEA Consultant** 

Re: ABC Order Monitoring Program Review

November 3, 2010 – November 5, 2010

# **Attorney/Client Privileged Communication**

### **PURPOSE OF REVIEW:**

The Review of the ABC Order Monitoring Program (OMP) was performed from November 3, 2010 to November 5, 2010 to ensure that the OMP is currently providing ABC with an appropriate system to monitor orders for controlled substances to comply with the requirements of 21 CFR § 1301.74 (b) and ABC policies and procedures.

## DOCUMENTS REVIEWED AND ABC EMPLOYEES INTERVIEWED:

The review included a review of numerous New Customer Due Diligence (NCDD) files, review of current default thresholds for each drug family and customer size, review of the ABC Do Not Ship List, several individual customer and drug reports created by Joe Tomkiewicz, review of CSRA 590 forms, the Retail Pharmacy Audit Checklist, a review of completed CSRA files for several new customers and several customers that have had an increase in thresholds over the past year.

The review included discussing the procedures with Ed Hazewski, Joe Tomkiewicz, Dave Breitmayer, and Kevin Kreutzer, all of which are involved in the daily operation of the ABC OMP. Much of the discussion with the OPM personnel centered around the reasons for the OMP, the need to be judicious about increasing thresholds, the need to be very detailed when performing an audit at retail pharmacies, and the incorporation of the rolling 30 day time frame for the OMP.

The OMP continues to be improved with increased focus on decisions backed with sales data and improved communication with ABC sales and compliance personnel in the DC's. The OMP is supported with robust data analysis from Joe Tomkiewicz.

#### NCDD FOR PRACTITIONERS:

A review of several of the CSRA 590P forms for practitioner due diligence indicated several issues related to establishment of accounts for practitioners.

The account for Dr. James Fang of Medina Ohio was approved even though the account address in Medina, Ohio is different from the address where Dr. Fang is registered with DEA. The ABC account for Dr. Fang has been initiated without a DEA number being included so that no controlled substances can be shipped.

The NCDD file for Dr. Frederick Briccetti at the Dana Farber Cancer Institute in Boston, MA indicated a DEA registration for Dr. Briccetti that was located in Concord, NH. The CSRA file approved the establishment of an ABC account for the Dana Farber Cancer Clinic in Boston, MA with the NH DEA registration. The clinic has a current ABC account, with an appropriate hospital/clinic DEA registration at the correct Boston, MA location.

The NCDD file for Laurence Hausman, MD at the Mt. Sinai Medical Center indicates that Dr. Hausman may be using the drugs supplied by ABC for Mt. Sinai at six (6) other practice locations in the New York metropolitan area. Using controlled substances purchased for one location for administration or dispensing to patient at another location without being separately registered by DEA at the other locations may be a violation of 21 CFR §1301.12.

The NCDD file for Irene Osborn MD, also at the Mt. Sinai Medical Center in New York, includes information that she intends to use the drugs obtained from ABC for overseas medical missions. There is no follow up to determine if she has obtained export authorization from DEA for any controlled substances.

These instances demonstrate the types of issues found with practitioner accounts that are not seen with retail pharmacy accounts. More information may need to be obtained before approving practitioner accounts.

#### NCDD FOR DISTRIBUTORS:

Several NCDD files were reviewed related to establishment of accounts for those registered with DEA as either distributors or manufacturers. From the information on the CSRA 590D, is was not clear if the potential customer has demonstrated to ABC that they have a significant OMP program, submit suspicious order reports to DEA, have an active new customer due diligence program for controlled substance customers, or if they ship controlled substances to those on the ABC Do Not Ship List.

The CSRA Form 590D includes some questions, 29 - 33, that are taken from the retail pharmacy CSRA 590 and although they apply directly to retail pharmacy practice, do not apply to distributors or manufacturers.

# **DEA SUSPICIOUS ORDER REPORTING:**

The suspicious orders that were reported to DEA for several months in 2010 were reviewed and compared to information in the LawTrac system. It appears that ABC is

appropriately reporting suspicious orders to DEA in compliance with 21 CFR §1301.74 and documenting the matters in LawTrac as necessary.

# **RECOMMENDATIONS:**

- 1. Concerning the NCDD files for practitioners, it is suggested that the CSRA Form 590P be revised to ask more direct questions specifically related to physicians.
- 2. When practitioners who are associated with large institutions request an account to order separately from the institution that has stocks of drugs, it should be determined why the physician needs to order drugs to be delivered to the institution. It may be necessary to coordinate such requests with the pharmacy or management of the institution.
- 3. Sales to other distributors or manufacturers of controlled substances provide ABC with both an opportunity and a risk. It is suggested that the due diligence review of a distributor or manufacturer be completed from the prospective of what would be required if the applicant was a subsidiary of ABC. These companies are under the same DEA requirements as ABC and must demonstrate to ABC results of their OMP program, not just state that they have a program. Information requested from potential distributor or manufacturer customers should include a request to the company for ARCOS reports for the past six (6) months. This will allow for verification of the sales information provided by the company to ABC and for a check of the DEA Do Not Ship List for customers of the distributor or manufacturer.
- 4. The CSRA Form 590D should be revised to include specific information directed at distributors and manufacturers.
- 5. The CSRA OMP staff should continue the monthly conference call to review the activities for the current month, assign follow up for specific issues, review the results of the past month's assignments, and assure that the staff is being consistent in handling of threshold requests.

#### **CONTACT INFORMATION:**

For questions or comments concerning this review of the ABC OPM, contact Michael Mapes, proposed to the ABC OPM, contact Micha

CC: Chris Zimmerman, VP CSRA

Steve Mays, Senior Director CSRA

Ed Hazewski, Manager, Diversion Control Program